

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9157

Bartle, J.

October 29, 2013

Verdean Daugherty ("Mr. Daugherty" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether Mr. Daugherty has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether he met his burden of proving that

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Weyth.

2. Marcia Daugherty, Mr. Daugherty's spouse, also has submitted a derivative claim for benefits.

his claim was not based, in whole or in part, on any intentional material misrepresentation of fact.³

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Richard Callihan, M.D. Dr. Callihan is no stranger to this litigation. According to the Trust, he has signed at least 1,089 Green Forms on behalf of claimants seeking Matrix Benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Based on an echocardiogram dated June 4, 2002, Dr. Callihan attested in Part II of claimant's Green Form that Mr. Daugherty suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$424,211.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, W. Marcus Brann, M.D., F.A.C.C., F.A.C.P., stated that Mr. Daugherty had moderate mitral regurgitation, which he measured to be 21%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In May, 2006, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its

4. Dr. Callihan also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). The Trust does not contest Dr. Callihan's representation that claimant had an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for Level II Matrix benefits.

auditing cardiologists.⁶ In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the Green Form representation that claimant had moderate mitral regurgitation. Specifically, Dr. Gillespie opined, "At most, there is mild [mitral regurgitation] however the Nyquist Limit is set at 45 cm/sec throughout the tape which is too low. Additionally the technician increased color gain inappropriately high from a setting of 3/16 to 3/21 causing excessive color persistence."

Based on Dr. Gillespie's finding, the Trust issued a post-audit determination denying Mr. Daugherty's claim. Pursuant to the Rules of Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Daugherty contested this adverse determination.⁷ In

6. The Trust originally forwarded Mr. Daugherty's claim for review in February, 2004. The auditing cardiologist accepted Dr. Callihan's Green Form representations, but the Trust later determined that the echocardiogram included inserted frames. Pursuant to Pretrial Order ("PTO") No. 5517 (July 27, 2005), claimant elected to have the inserted frames removed and the claim re-audited. Thus, in March, 2006, the Trust forwarded Mr. Daugherty's claim, including the redacted echocardiogram, for audit. Although the auditing cardiologist again agreed with Dr. Callihan's Green Form representations, the Trust submitted the claim for review by the Consensus Expert Panel ("CEP") pursuant to PTO No. 6100 (Mar. 31, 2006) (adopting Court Approved Procedure ("CAP") No. 11). Based on the recommendation of the CEP, Mr. Daugherty's claim and redacted echocardiogram were submitted to another auditing cardiologist, Dr. Gillespie, for review. Dr. Gillespie's review is the subject of this show cause proceeding.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit
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contest, claimant argued that his claim should be paid because the Trust's first auditor of the redacted echocardiogram found a reasonable medical basis for Dr. Callihan's Green Form representation. In addition, Mr. Daugherty asserted that the third audit, conducted by Dr. Gillespie, should be disregarded because CAP No. 11 specifically prohibits more than two audits of a claim. Finally, claimant argued that there was a reasonable medical basis for Dr. Callihan's Green Form representation because two of the Trust's auditors agreed with his finding.

The Trust then issued a final post-audit determination, again denying Mr. Daugherty's claim. The Trust argued that PTO No. 5517 did not require Mr. Daugherty's claim to be paid simply because it received a favorable audit. In addition, the Trust asserted that Mr. Daugherty's claim was properly the subject of the Trust's Quality Assurance Program and CAP No. 11 because the audit of Mr. Daugherty's echocardiogram prior to removal of inserted frames was a nullity. The Trust also contended that CAP No. 11's prohibition on more than two audits was not violated because the audit of Mr. Daugherty's claim pursuant to PTO No. 5517 was the first audit of his redacted echocardiogram. Finally, the Trust argued that the audit of his original echocardiogram and the first audit of his redacted echocardiogram did not provide a reasonable medical basis for Mr. Daugherty's claim because Dr. Gillespie determined that Dr. Callihan's

7. (...continued)
Rules contained in PTO No. 2807 apply to Mr. Daugherty's claim.

representation of moderate mitral regurgitation was the result of conduct beyond the bounds of medical reason.

Mr. Daugherty disputed the Trust's final determination and requested that his claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Daugherty's claim should be paid. On May 14, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7194 (May 14, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, in which he disagreed with the medical findings of the auditing cardiologist and the Trust's characterization of those findings. The Trust submitted a reply on August 3, 2007 which incorporated the final post-audit determination. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge -- helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

As noted above, the issue presented for resolution of this claim is whether Mr. Daugherty has demonstrated a reasonable medical basis to support his claim for Matrix Benefits and, if so, whether he met his burden of proving that his claim was not based, in whole or in part, on any intentional material misrepresentation of fact. Where the Trust's Post-Audit Determination finds intentional misrepresentation of fact, the claimant has the burden of proving that all representations of material fact in connection with his claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer with no intentional material misrepresentation of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

There was an abnormally low Nyquist limit of 45 cm/sec at 19 cm depth in the parasternal and apical views. There was high color gain with color artifact seen within the myocardium and outside of the heart. There was abnormal pixilation and stuttering of images related to persistence causing color artifact.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram. He determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

Mitral regurgitation could be seen in the parasternal long-axis and apical views. I digitized those cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. In spite of increased artifact due to excessive color gain, persistence and low Nyquist, I was able to evaluate the mitral regurgitant jet in several cardiac cycles in the mid portion of systole. The largest representative RJA was 4.6 cm². The RJA was most impressive in the apical four chamber view. A smaller RJA was noted in the apical two chamber view. I determined that the LAA measured 28.1 cm². Therefore, the largest representative RJA/LAA ratio was 16%. This ratio did not approach 20%. Most of the RJA/LAA ratios were less than 13%.

After reviewing the entire show cause record, we find that claimant has not established he is entitled to Matrix

Benefits. As an initial matter, we reject Mr. Daugherty's contention that the Trust improperly subjected his redacted echocardiogram to review pursuant to CAP No. 11 in violation of the supposed two-audit limitation.

In PTO No. 5517, we observed that echocardiograms with inserted frames, like Mr. Daugherty's original echocardiogram, "are contrary to ordinary clinical practice and interfere with the integrity of the echocardiogram as a medical record." Mem. in Supp. of PTO No. 5517 at 2. In addition, we noted that "any interference with the date and time sequence of the frames impedes the ability to determine accurately a claimant's actual medical condition. The insertions can make undeserving claimants appear to qualify for matrix benefits" and "undermine the integrity of the compensation process under the Trust." Id. at 4. Nevertheless, after hearing from all interested parties, including counsel for Mr. Daugherty, we recognized that some of the class members who originally relied on these echocardiograms may have legitimate claims under the Settlement Agreement. Thus, we permitted these claimants to have an audit of their echocardiogram after the offending inserted frames had been removed.

Given the circumstances surrounding the submission and audit of his original echocardiogram, we find the initial audit of Mr. Daugherty's redacted echocardiogram constitutes a first audit. Therefore, it was not improper to subject Mr. Daugherty's

redacted echocardiogram to re-audit following the CEP's review and recommendation.

We also disagree with Mr. Daugherty that his claim must be paid based on the initial audit of his redacted echocardiogram pursuant to PTO No. 5517. Specifically, Mr. Daugherty argues that PTO No. 5517, which states that "any class member whose claim is compensable under the criteria of the Settlement Agreement after re-audit shall be paid," PTO No. 5517 at 2, exempts his claim from further scrutiny if the initial audit of his redacted echocardiogram is favorable. We do not agree. There is nothing in the language of PTO No. 5517 that suggests a favorable initial audit of a redacted echocardiogram should not be subject to all the procedures we have adopted as part of our continuing jurisdiction over the Settlement Agreement, including, among others, CAP No. 11. Thus, this matter is properly before us for review.⁹

In addition, we find that claimant has not established a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of

9. In any event, we previously have stated that "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists who determined that there is no reasonable medical basis for a claim simply because the claim has previously passed audit.

these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously have explained, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Gillespie and Dr. Vigilante found that claimant's sonographer improperly used a decreased Nyquist setting, increased color gain, and excessive color persistence. These characteristics distort the supposed regurgitant "jet" in claimant's echocardiogram.

Notwithstanding these deficiencies, Dr. Gillespie and Dr. Vigilante determined that Mr. Daugherty's echocardiogram demonstrated at most mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Mr. Daugherty had moderate mitral regurgitation.¹⁰

10. Despite an opportunity to do so, claimant did not submit a
(continued...)

Specifically, Dr. Vigilante explained that "the largest representative RJA/LAA ratio was 16%" and that "[m]ost of the RJA/LAA ratios were less than 13%."

Claimant does not substantively challenge the specific findings of Dr. Gillespie and Dr. Vigilante regarding the manner in which his echocardiogram was conducted or his level of mitral regurgitation was evaluated. Rather, claimant refers only to the results of the initial audits of his unredacted and redacted echocardiograms by the Trust. Without identifying some specific error by the auditing cardiologist and the Technical Advisor, claimant cannot meet his burden of proof in establishing that his claim is payable.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation and that he was thus eligible for Matrix Benefits.¹¹ Therefore, we will affirm the Trust's denial of Mr. Daugherty's claim for Matrix Benefits and the related derivative claim submitted by his spouse.

10. (...continued)
response to the Technical Advisor Report. See Audit Rule 34.

11. Thus, we need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Mr. Daugherty's claim.